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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/661,437	09/12/2003	Benjamin J. Feldman	12008.32USC6	8139

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Attention: Mara E. Liepa
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EXAMINER	
NOGUEROLA, ALEXANDER STEPHAN	

ART UNIT	PAPER NUMBER
1795	

MAIL DATE	DELIVERY MODE
06/02/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/661,437	FELDMAN ET AL.	
	Examiner	Art Unit	
	ALEX NOGUEROLA	1795	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-17* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-17* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *23 May 2005* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *12/15/03*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☒ Other: *IDS of 10/25/07*

DETAILED ACTION

Claim Rejections - 35 USC § 103

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

2. The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

3. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to

consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

4. Claims 1, 4-6, 9-13, 16, and 17 are rejected under 35 U.S.C. 103(a) as being unpatentable over the JPO computer translation of Tadahisa et al. JP 09-101280 A ("Tadahisa") in view of Jobst et al., "Mass producible miniaturized flow through a device with a biosensor array, Sensors and Actuators B 43 (1997) 121-125 ("Jobst").

Addressing claims 1 and 14, Tadahisa discloses a sensor strip for determining the concentration of an analyte in a sample, the sensor strip comprising:

(a) a first substrate (16) having a proximal end and an opposite distal end, the distal end being configured and arranged for insertion into a sensor reader, the first substrate defining a first side edge and a second side edge of the sensor extending from the proximal end to the distal end of the first substrate (drawings 3a and 3b) ;

(b) a second substrate (19) positioned over the first substrate (drawing 3b);

(c) a spacer (13) between the first and second substrates (drawing 3b) defining:

(i)a first aperture (14A) along the proximal end of the sensor (drawing 3b),

(ii) a second aperture (either end of inspection space 14b) along the first side edge of the sensor (drawing 3b), and

(iii) a sample chamber (14) extending from the first aperture to the second aperture, the sample chamber comprising a measurement zone;

(d) at least one working electrode (17, 17a) on the first substrate; and

(e) at least one counter electrode (18) on the first substrate

Tadahisa identifies electrode 18 as an "amendment" (interference) electrode and electrode 15, which is on the second substrate, as the cathode (counter) electrode. As a first matter these labels are intended use that do not actually limit the electrodes since the interference electrode could be used as a counter electrode and the counter electrode could be used as an interference electrode. In any event, barring a contrary showing, to interchange interference electrode for the counter electrode and thus place the counter electrode on the first substrate is just mere rearrangement of parts that would have no discernable effect upon the measurements.

Tadahisa does not mention the volume of the measurement zone. However, it is clearly very small as the width of the apertures (and sample chamber) is only 0.2 micrometers and the height of the apertures (and sample chamber), which is the same as the thickness of the spacer, is only 20-200 micrometers. See paragraph [0014] in

the Detailed Description. Since it has been held that mere change in size is not in itself patentable (MPEP 2144.04.IV. A) and Tadahisa's dimensions suggest a volume of less than 1 microliter or very close to 1 microliter, as the two stated dimensions are each less that 1 millimeter (1 microliter = 1 mm x 1 mm X 1mm), Applicants' limitation of having the measurement zone be no more than 1 microliter is, barring evidence to the contrary, such as unexpected results, a mere change in size capable of being achieved by one of ordinary skill in the art at the time of the invention with available manufacturing techniques of that time. Jobst, for example, discloses a measurement zone comprising an array of enzyme electrodes, a reference electrode, and a counter electrode having a total internal volume of only 2.1 microliter. See the abstract; Figure 2; and the first full paragraph in the second column on page 122. By reducing the size of the sample chamber, less sample will be need, which means less pain and inconvenience to patients if regular blood glucose measurements are need for diabetes monitoring, for example.

Tadahisa also does not mention whether a portion of the counter electrodes is located 25-1000 micrometers from a portion of the at least one working electrodes; however, as with the volume limitation, this is again a mere obvious change in size, which would help reduce the measurement volume. It should be noted that the reference and working electrodes in Jobst appear to be less than 1000 micrometers apart as the length of the cell is 5 mm and the working electrodes are 0.5 mm in width. See the first full paragraph in the second column on page 122 and the second full paragraph in the second column on page 121.

For claim 14 also note that the preamble limitation of the sensor strip being for measuring glucose concentration in a blood sample is an intended use of which the sensor strip of Tadahisa as modified by Jobst is capable of since although Tadahisa does not specifically mention using a blood sample with glucose analyte, glucose is a disclosed analyte (Tadahisa paragraph [0026] in the Detailed Description) and blood sample is implied as the biosensor can be configured to prevent hemoglobin from reaching the working electrodes. See paragraph [0027] in Means. Also note that Jobst took measurements on blood sample for glucose analyte. See the first column on page 123.

Addressing claims 4, 5, 16, and 17, for the additional limitations of these claims note that although the total internal volume in Jobst is 2.1 microliters, the measurement zone, which is bounded on the bottom by the counter electrode (Figure 2) has a volume of 1.5 microliters (flow chamber is 5x1x0.3 mm^3) and contains four individual enzyme electrodes and a reference electrode in addition to the counter electrode. See the first full paragraph in the second column on page 122 and Figure 2. Thus, especially since Tadahisa discloses that the measurement zone may have a width of only 0.2 micron and a height of 20 microliters, the claimed volume ranges of claims 4 and 5 are just mere changes in size within the skill of one of ordinary skill in the art at the time of the invention to perform.

Addressing claims 6 and 9, for the additional limitations of these claims see in Tadahisa paragraph [0026] in the Detailed Description.

Addressing claims 10 and 11, for the additional limitations of these claims see in Tadahisa drawings 3(a) and 3(b).

Addressing claim 12, for the additional limitation of this claim note that although the rejection of claim 1 argued for interchanging the interference electrode, which is a second working electrode, for the counter electrode, all three electrodes could be placed on the first substrate, with appropriate adjustment of the electrode dimensions. Again, this is just rearrangement of parts that would not discernibly affect the measurement results.

Addressing claim 13, for the additional limitation of this claim note that although Tadahisa does not specifically mention using a blood sample with glucose analyte, glucose is a disclosed analyte (Tadahisa paragraph [0026] in the Detailed Description) and blood sample is implied as the biosensor can be configured to prevent hemoglobin from reaching the working electrodes. See paragraph [0027] in Means. Also note that Jobst took measurements on blood sample for glucose analyte. See the first column on page 123.

5. Claim 2 is rejected under 35 U.S.C. 103(a) as being unpatentable over the JPO computer translation of Tadahisa et al. JP 09-101280 A ("Tadahisa") in view of Jobst et al., "Mass producible miniaturized flow through a device with a biosensor array, Sensors and Actuators B 43 (1997) 121-125 ("Jobst") as applied to claims 1, 4-6, 9-13, 16, and 17 above, and further in view of Ikeda et al. US 5,582,697 ("Ikeda").

Although Tadahisa as modified by Jobst discloses providing an additional electrode it is an interference electrode.

Ikeda discloses a test strip electrochemical biosensor comprising an indicator electrode (7) on a substrate positioned relative to the sample chamber to determine when the sample chamber contains sample. See the abstract and Figure 1. It would have been obvious to one with ordinary skill in the art at the time of the invention to provide an indicator electrode as taught by Ikeda in the invention of Tadahisa as modified by Jobst because then the detection of sample sufficiency will not affect the measurements. See in Ikeda col. 02:17-30 and col. 04:24-36.

6. Claims 3 and 15 are rejected under 35 U.S.C. 103(a) as being unpatentable over the JPO computer translation of Tadahisa et al. JP 09-101280 A ("Tadahisa") in view of

Jobst et al., "Mass producible miniaturized flow through a device with a biosensor array, Sensors and Actuators B 43 (1997) 121-125 ("Jobst") as applied to claims 1, 4-6, 9-13, 16, and 17 above, and further in view of Fujiwara et al. US 6,004,441 ("Fujiwara") and Kurnik et al. US 5,989,409 ("Kurnik").

Addressing claims 3 and 15, as discussed in the rejections of claims 1 and 14 in light of the sample chamber width and height dimension disclosed by Tadahisa and the small total internal volume disclosed for the sensor array of Jobst, the claimed distance between the electrodes is effectively just a matter of reducing the size of the sensor. Moreover, as shown by Fujiwara it was known at the time of the invention how to make electrodes in test strip electrochemical biosensors only 70 micrometers apart or even 50 microns apart. See in Fujiwara the abstract; Figures 1(a) – 1(d); and col. 02:40-59; and in Kurnik the abstract; Figures 1A, 1B, and 3A; and col. 04:50-55; col. 07:04-45; and col. 13:41-44.

7. Claims 7 and 8 are rejected under 35 U.S.C. 103(a) as being unpatentable over the JPO computer translation of Tadahisa et al. JP 09-101280 A ("Tadahisa") in view of Jobst et al., "Mass producible miniaturized flow through a device with a biosensor array, Sensors and Actuators B 43 (1997) 121-125 ("Jobst") as applied to claims 1, 4-6, 9-13, 16, and 17 above, and further in view of Diebold et al. US 5,437,999 ("Diebold") and Gregg et al. US 5,262,035 ("Gregg")

Tadahisa as modified by Jobst does not disclose a non-leachable redox mediator or an osmium redox mediator.

Diebold discloses a test strip electrochemical biosensor comprising a non-leachable redox mediator and an osmium redox mediator. See the abstract; Figure 6; col. 10:14 – col. 12:18. It would have been obvious to one with ordinary skill in the art at the time of the invention to use a non-leachable redox mediator or an osmium redox mediator as taught by Diebold in the invention of Tadahisa as modified by Jobst because as taught by Gregg, which discloses a enzyme electrode comprising a non-leachable redox mediator or an osmium redox mediator (the same as used by Diebold),

There are several advantages to an enzyme electrode system based on a crosslinked redox polymer. First, the use of crosslinked films on the electrode surface eliminates the requirement for a membrane which is often required in conventional systems to confine the enzyme to a small volume close to the electrode surface. Thus, the use of crosslinked redox films tends to simplify the design and the manufacture of the enzyme electrode. Second, the process by which the electrodes are produced is relatively simple, reproducible and can be easily automated. Third, the enzyme may be stabilized by its interaction with the polymer matrix, thus retarding thermal denaturation. Also, it may be physically protected from attack by proteases in solution which are too large to diffuse through the polymer film. Fourth, the versatility of these materials allows the tailoring of properties for specific applications. For example, the redox potential, the hydrophilicity and the charge on the polymer may be adjusted as may the crosslinking method. Fifth, the transport of interfering electroreactive substances to the electrode surfaces and/or their adsorption on these surfaces can be retarded by appropriate design of the polymer. Sixth, the resulting electrodes are in general mechanically rugged and typically exhibit excellent stability during storage. Seventh, although enzymes are known to rapidly denature on many surfaces, the polymer apparently tends to protect the enzymes from the surface of the electrode. Thus, virtually any electrode surface may be used for these enzyme electrodes. Additionally, such polymers in general appear to be substantially biocompatible.

See col. 07:19-50; the abstract; and col. 05:39-54.

Information Disclosure Statement

8. The Examiner did not initial the foreign patent documents an non-patent literature listed on the Information Disclosure Statement of December 13, 2003 because the Examiner was not able to obtain the paper parent application 09/594,285 in which these references are supposed to be located. The Examiner is still attempting to locate this application file and will contact Applicants if not located by the time Applicants respond to this Office action.

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to ALEX NOGUEROLA whose telephone number is (571) 272-1343. The examiner can normally be reached on M-F 8:30 - 5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, NAM NGUYEN can be reached on (571) 272-1342. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Alex Noguerola/
Primary Examiner, Art Unit 1795